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INTERNATIONAL LIVESTOCK RESEARCH INSTITUTE

ILRI policy procedure on obtaining prior informed consent in research activities

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		IMC approval date	
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Revision history

Version No.	Effective date	Approved by and date	Summary of changes	Next scheduled review
1.0	01 February 2020	ILRI IMC 22 January 2020		

Related documents

ILRI policy(ies)	Research compliance
Global framework	
CGIAR framework/policy	
ILRI procedures	Disclosure of confidential research data Guidelines on use of photography
Other relevant documents	
Appendix	

Contents

Section 1: Executive summary

1.1 Context and purpose

Prior informed consent (PIC) is an ethical and legal requirement for research involving human participants. It is the process where a prospective research participant is fully informed about all aspects of a project, putting the person in a position to make an informed decision about his/her participation in the study, allowing him/her to voluntarily confirm his/her willingness to participate in a given project. The concept of informed consent is embedded in the principles of Nuremberg Code, The Declaration of Helsinki and The Belmont Report. ILRI's values have at their core the respect and protection of research participants, most of which are vulnerable communities in poor countries. As such, ILRI takes very seriously professional and ethical practice when it comes to engaging and working with participants as part of its research. The ILRI's IREC requires investigators to obtain prior informed consent from each prospective study participant.

These procedures have been developed to provide guidance to ILRI scientists on best practices for recruitment of research participants and help ensure quality and consistency in application of the prior informed consent process across ILRI's research projects.

1.2 Scope

These policy procedures provides guidelines to ILRI staff on sharing of confidential data collected within ILRI research activities (this excludes data from ILRI development activities, which is instead covered by ILRI's data protection and privacy policy). These research activities are approved by ILRI's research compliance process and the Institutional Research Ethics Committee (IREC), and hence these guidelines accompany ILRI's research compliance policy. These procedures are to be adhered to when applying for IREC's ethics approval.

1.3 Primary and other audiences

The primary audience for this document is all people working in any research activity for which ILRI is responsible, that requires IREC's ethical approval or ethical approval for another relevant board (i.e. another institution or country-specific boards).

1.4 Key changes since last version

Not applicable

1.5 Summary of key country/regional-specific differences in application

These guidelines must be complemented with any additional requirements specific to the locations where the research work is being implemented. This is normally dictated by the country or regional specific research ethics requirements in the locations where the work is being conducted. The guidelines must also be adapted to meet the expectations and cultural norms in the communities where the work is being done.

Section 2: The procedures

2.1 Elements of informed consent

The contents of informed consent should follow the guidance provided by the WMA Declaration of Helsinki – Ethical principles for medical research involving human subjects (http://www.wma.net/en/30publications/10policies/b3/).

In summary, informed consent should provide the following information to prospective participants:

1. The aims of the study and the methods to be used
2. The sources of funding and possible conflicts of interest
3. The institutional affiliations of the researcher
4. The anticipated benefits and potential risks
5. The discomfort it may entail/the time it will take
6. Any post-study provisions
7. The right to abstain from participating, or to withdraw from it at any time, without reprisals

Additionally, it is required that the informed consent process includes the following:

8. The opportunity to ask questions
9. The way in which the study will be reported and shared
10. The person to report any concerns about the study to i.e. someone from the research team and someone from the ethics committee.
11. Ensure and provide confirmation on the protection of confidentiality and privacy of the research subjects and their personal information.

The informed consent process should be administered in a format that fosters understanding by the prospective participants. This includes using the most appropriate local language and either written or verbal communication, whichever suits the local context. The use of visual aids such as pictures, photos or drawings should be considered whenever they could help improve understanding by prospective participants (see Appendix 3.2 for examples of consent forms).

2.2 Consent from minors and mentally disabled individuals

- In the case of children aged 12 years or younger, consent should be sought from parent/guardian.

- Where a proposed participant is a minor aged thirteen (13) to seventeen (17) years of age who is possessed of sufficient understanding to grant informed consent but is precluded from granting such consent solely on the grounds of age, the PI must obtain a written assent from the minor, in addition to permission from a parent, guardian or any person in *loco parentis.*
- A *mature minor* is any individual less than eighteen (18) years of age who is married, pregnant, a mother or a household head. A mature minor is permitted to give consent for him or herself and for their child/children but not allowed to consent on behalf of a sibling.
- Where a proposed participant is aged thirteen (13) and above and is not able to grant informed consent due to intellectual disability or a medical condition, consent should be sought from a parent, guardian or any person in *loco parentis*.

2.3 Documentation of consent

- Individual informed consent must be documented by use of written (signature or fingerprint) approved consent. (See exceptions below)
- The consent form must be signed and dated by the research participant or research participant's legally authorized representative at the time of consent.
- A copy of the information sheet part of the consent form should be given to the participant.
- Documentation of consent, especially an individual's signature, should be kept in a locked cabinet or a place inaccessible to people outside of the research team, separate from research tools (e.g. survey questionnaires) so as to preserve the anonymity of participants.
- In some instances (e.g. during focus groups discussions, or other research activities that are conducted with groups as opposed to individuals) the informed consent process could be administered collectively, whenever the process is culturally acceptable and the risk of coercion from collective consent is negligible. In these cases, evidence of consent should be recorded for each individual and recorded either individually or collectively (i.e. in a table where all names are listed and appropriate evidence of written consent (e.g. signature, fingerprint) is included). The other provisions on these guidelines still apply to these cases.

2.4 Waiver of informed consent

- **Waiver of written consent**. The need for written documentation of consent (i.e. participants to sign upon informed consent) may be waived by IREC in specific circumstances. In these cases, individual **verbal consent** (witnessed and documented) will be required. This waiver will only apply subject to the condition that requesting the participant's involvement in formal documentation of consent (i.e. providing a signature) might cause significant discomfort to

participants due to literacy (i.e. marking a form without being able to read it), cultural significance of such an act (i.e. some cultures reserve this form of contract-style agreement for weddings and other significant life events), fear due to history of signatures being misused by those more powerful (Marshall, 2007), or concerns around confidentiality (the integrity of the confidentiality). In such cases, the following should be observed:

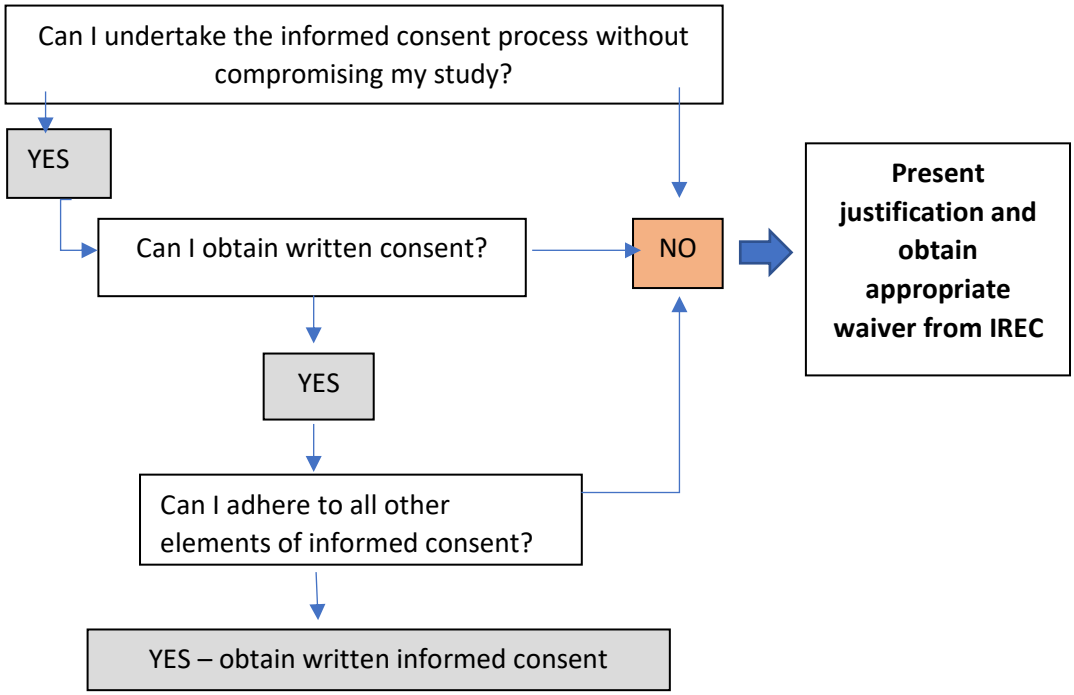
- Researchers should provide IREC with sound evidence, when applying for ethics approval, on the reason that justifies the need to waive written consent. This could include evidence that the participants or their community express a preference for verbal consent versus written consent (i.e. a letter from a village leader, or a community representative).
- The waiver will not affect the rights and welfare of the research participants.
- More than one researcher is present, who can attest to and sign to verify the consent. In the absence of this, a witness from the community can attest to and sign to verify consent.
- The research presents no more than minimal risks and involves procedures for which consent would not normally be obtained outside the research context.

2.5 Waiver of other elements of the informed consent

The IREC may **waive any other or all the elements** of informed consent as above, subject to the conditions that the:

- research presents no more than minimal risk, AND
- signed consent is the only record linking the study participant to the research and is the primary risk of breach of confidentiality by the research, AND
- proposed plan for the protection of privacy and confidentiality is adequate, AND
- waiver will not affect the rights and welfare of the research participants, AND
- when applicable, research participants will be given additional pertinent information after their participation (the waiver shouldn't prevent participants to get access, individually or collectively, to any relevant information that comes up after their participation in the study), AND
- The research could not practicably be carried out without the waiver (for example, where the research involves only excerpting data from subjects' records; when obtaining informed consent may compromise the validity of the data, e.g. subjects changing behavior because of knowing about the project).

2.6 Decision tree on the need for informed consent



2.7 Administering informed consent

- All consent documents should be translated into relevant local dialects, either as a written document or at the time of administration of consent, by enumerators fluent in local languages and trained in the administration of consent forms.
- It is the researchers' responsibility to ensure that translations are accurate and that the informed consent process is administered by a member of the research team or enumerator who has been trained on how to foster autonomy and to appropriately convey the project information. It is not appropriate to use untrained lay people for this process.
- Simple language should be used highlighting the main points of relevance to the informed consent process.
- Researchers should use the most adequate form of administering consent, to foster participant's understanding. These should be also aligned with social and cultural preferences. For example, written forms would be appropriate in certain contexts. The use of graphics and/or pictorial information may be more adequate in other context, e.g. where literacy levels are lower.
- Consider keeping a record of number who consent and those that do not consent, as this can inform the relevance of the work and the appropriateness of the proposed activities.

2.8 Points to consider when planning and conducting informed consent

- Does the participant have the ability to exercise their right to autonomy*?

  Adjust the consent process to the needs of the individual, so that he/she can understand what's being explained; identify the person that should provide consent on this person's behalf

- Is a one-off signing of a form enough?

  Consider if consenting participants require regular contacts to check on their willingness to remain in the study.

- Has the participant understood what is involved in the study?

  Assess the level of comprehension and engagement, provide feedback and talk through any misunderstandings.

*Belmont Report (1974): 'An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation.'

Section 3: Appendix

3.1 Definitions

Informed consent: process by which a research project is explained to a prospective participant and free, well-informed agreement to participate is obtained

3.2 Tools and forms

Example consent forms can be obtained from the Research Compliance Secretariat at: ILRIResearchcompliance@cgiar.org